ASTRAZENECA PLC
Form 6-K
September 27, 2013

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of September 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

MARKETING AUTHORISATION APPLICATION FOR NALOXEGOL ACCEPTED BY EUROPEAN MEDICINES AGENCY

AstraZeneca today announced that the European Medicines Agency (EMA) has accepted the Marketing Authorisation Application (MAA) for naloxegol, an investigational peripherally-acting mu-opioid receptor antagonist, which has been specifically designed for the treatment of opioid-induced constipation (OIC) for adult patients 18 years and older, including patients with inadequate response to laxatives.

The MAA filing was based on comprehensive data from the core Phase III KODIAC programme, comprised of four clinical trials designed to investigate the safety and efficacy of naloxegol for the treatment of OIC. Two pivotal Phase III studies, KODIAC-04 (n=652) and KODIAC-05 (n=700), both 12-week, multicentre, randomised, double blind, placebo-controlled trials, evaluated 12.5 mg and 25 mg doses of naloxegol administered once-daily. KODIAC-07 was a 12-week safety extension of KODIAC-04, and KODIAC-08 (n= 534) was an open-label, randomised, 52-week, long-term safety trial.

Naloxegol has the potential to be the first once-daily oral peripherally-acting mu-opioid receptor antagonist medication for patients with OIC. Naloxegol was developed using Nektar's oral small molecule polymer conjugate technology.

Naloxegol is covered by the exclusive worldwide license agreement announced on 21 September 2009 between AstraZeneca and Nektar Therapeutics. Under the terms of the recently amended license agreement, AstraZeneca will make a $25 million milestone payment to Nektar within five business days of acceptance of the MAA by the EMA.

NOTES TO EDITORS

About Opioid-Induced Constipation

OIC is a condition caused by prescription opioid pain medicines. Opioids bind to specific proteins called opioid receptors. When the opioids bind to certain opioid receptors in the gastrointestinal (GI) tract, constipation may occur. Opioid-induced constipation is a result of increased fluid absorption and lower GI motility due to opioid receptor binding in the gastrointestinal tract.

Globally, approximately 40-50% (28-35 million) of patients taking opioids for long-term pain develop opioid-induced constipation. About 40-50% (11-18 million) of those OIC sufferers achieve the desired treatment outcomes with current options that include over-the-counter and prescription laxatives.

About Nektar
Nektar Therapeutics (NASDAQ: NKTR) is a biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms. Nektar has a robust R&D pipeline of potentially high-value therapeutics in oncology, pain and other therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for naloxegol (NKTR-118), an investigational drug candidate, which has completed Phase 3 development as a once- daily, oral tablet for the treatment of opioid-induced constipation. This agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of naloxegol and an opioid. NKTR-181, a novel mu-opioid analgesic candidate for chronic pain conditions, is in Phase 2 development in osteoarthritis patients with chronic knee pain. NKTR-192, a novel mu-opioid analgesic in development to treat acute pain is in Phase 1 clinical development. In oncology, etirinotecan pegol (NKTR-102) is being evaluated in a Phase 3 clinical study (the BEACON study) for the treatment of metastatic breast cancer and is also in Phase 2 studies

for the treatment of ovarian and colorectal cancers. In anti-infectives, Amikacin Inhale is in Phase 3 studies conducted by Bayer Healthcare to treat patients with Gram-negative pneumonia.

Nektar's technology has enabled eight approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including UCB's Cimzia® for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS® for hepatitis C and Amgen's Neulasta® for neutropenia. Additional development-stage products that leverage Nektar's proprietary technology platform include Baxter's BAX 855, a long-acting PEGylated rFVIII program, which is in Phase 3 clinical development.

Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at http://www.nektar.com

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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27 September 2013

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 27 September 2013

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary